

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA ex rel.  
PEGGY RYAN,

Plaintiffs,

Case No. 05-cv-3450

v.

ENDO PHARMACEUTICALS, INC.,

Defendants.

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**DECLARATION OF ALFRED SCUDIERI IN SUPPORT OF  
PEGGY RYAN'S MOTION FOR RELATOR SHARE AWARD**

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I, Alfred Scudieri, do hereby declare and state:

1. I am the Chief Investigator at the law firm of James, Hoyer, Newcomer & Smiljanich, P.A. ("James Hoyer"), in Tampa, Florida. The James Hoyer firm served as counsel for Relator Peggy Ryan in the above-captioned case. Our firm specializes in consumer fraud and whistleblower litigation under the federal and state False Claims Acts.
2. By way of background, I joined the James Hoyer firm in 1995 after retiring from the FBI with thirty years of service in New York City, Alabama, Puerto Rico, Washington, DC and ultimately, Tampa, Florida. In 1989, I was named the Supervisor of the White Collar Crimes/Fraud Unit in Tampa, specializing in bank fraud, securities fraud, and governmental fraud. In 1992, I was recognized as Florida's Federal Law Enforcement Officer of the Year after successfully supervising a major fraud/terrorism investigation. I held the position of Supervisor of the White Collar Crimes Unit until my retirement in 1995.

3. In 2005, I was contacted by Peggy Ryan regarding an illegal off-label marketing scheme allegedly perpetrated by her employer, Endo Pharmaceuticals ("Endo"). Based on my

years of experience working for the FBI and evaluating False Claims Act cases at James Hoyer, I determined Ryan to be credible, honest and extremely knowledgeable about the alleged Endo fraud scheme. The James Hoyer firm agreed to represent Ryan on a contingency basis, in filing a False Claims Act case against Endo Pharmaceuticals.

4. The James Hoyer firm filed Ryan's case against Endo on July 5, 2005 in the United States District Court for the Eastern District of Pennsylvania (EDPA). The suit alleged that Endo Pharmaceuticals was knowingly and intentionally defrauding government health care programs by marketing its flagship drug, Lidoderm, for unapproved uses. The Complaint (Dkt. 1) alleges specific examples of Endo's off-label marketing scheme, including: (1) instructing sales representatives to promote Lidoderm for off-label uses; (2) creating and self-funding studies and articles regarding the effectiveness of Lidoderm for off-label uses; (3) falsely seeking approval of Lidoderm as an "orphan drug" to maximize tax and patent protections; and (4) illegally paying kickbacks and offering incentives to induce physicians to prescribe Lidoderm. Ryan made these allegations based on her first-hand experiences as a Specialty Sales Representative for Endo.

5. Before filing the case, the James Hoyer firm made a pre-filing disclosure to Albany FBI Agent Chris Mulhall on June 20, 2005. Immediately following the filing of the complaint, I accompanied Ryan to her first meeting with the government. In that meeting, and in a subsequent relator's meeting on November 3, 2005, I assisted Ryan in presenting the government with a number of documents supporting her allegations, including: Restricted Materials Logs; call plans; scorecard sheets; excessive sales goals; Endo-funded off-label studies; training, sales and promotional materials; sample Lidoderm packets; and internal emails and memoranda regarding the off-label sale of Lidoderm.

6. Since my first telephone calls to the government in June 2005, until the present, I have never received any indication the government had knowledge of the Lidoderm off-label marketing scheme prior to the disclosure of Ryan's allegations.

7. From 2005 through the present, the James Hoyer firm has worked hand-in-hand with Ryan on this case. Our firm has logged more than 7,000 hours of attorney, paralegal, and investigator time in this action. Our work included conducting legal research regarding previous off-label cases; preparing memoranda and reports regarding Lidoderm's indications in various formularies; preparing damage calculations; reviewing documents, emails, voicemails, and sales materials provided by Relator; drafting and filing the original and three amended complaints and corresponding written disclosure statements; participating in interviews with the Relator in New York, Florida, and Pennsylvania; meeting and corresponding with government attorneys, investigators and auditors from various agencies including the U.S. Department of Justice, United States Attorney's Offices in the EDPA and Northern District of New York (NDNY), the Federal Bureau of Investigation, the Food & Drug Administration, the Department of Health and Human Services and the offices of various state attorneys general.

8. The James Hoyer firm has several unique aspects of case management which were instrumental in moving this case toward a successful resolution. As Chief Investigator, I oversee a video production team which is comprised of Emmy Award-winning directors and video editors. In late 2011 and 2012, the James Hoyer firm sensed the government's investigation was stalling as a result of the turnover of investigators and prosecutors. Personnel new to the case needed to be brought up to speed regarding the magnitude and significance of Ryan's allegations. In an effort to assist the government with this endeavor, the James Hoyer video team worked with Ryan to produce an 18-minute documentary-style video which

summarized Ryan's case, the supporting evidence, the 200+ hours of recordings made by Ryan for the FBI, and the amount of damages at issue in the case. The video was circulated to government personnel including AUSAs Marilyn May, Jerry Sullivan, Peg Hutchinson, Sarah Lord and Jacquith Grant and FBI Agent Chris Mulhall among others. The video was also placed on a secure web page which could be accessed by these individuals. Shortly thereafter, the James Hoyer video production team produced a second documentary-style video which highlighted Endo's use of paid physicians who created scientifically-questionable studies in exchange for royalty payments. This video, which emphasized the complexity with which Endo planned and executed its off-label marketing scheme, was also made available to the above-named individuals. A copy of the James Hoyer documentary video is attached to this declaration as Exhibit 1.<sup>1</sup>

9. The James Hoyer firm also uses a proprietary case management system called Genu to manage and organize the large volume of information and data which naturally arises from complex False Claims Act investigations. The Genu system is built around developing a narrative to support the allegations in a case with documents and linkable knowledge. The Genu system includes document storage where all documents associated with the case are catalogued, and a "Hopper" system where salient information can be gleaned from each document and stored in a useable, accessible manner. James Hoyer provided user access to the line attorneys working on the Endo case. An excerpt of the Genu narrative related to various techniques of off-label marketing is attached to this declaration as Exhibit 2.

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<sup>1</sup> A placeholder page has been filed electronically with this declaration. A DVD of the documentary will be mailed to Judge Kelly's chambers and served upon all other parties of records.

10. Relator Peggy Ryan and the James Hoyer firm closely assessed the proposed settlement agreement to determine whether it was fair, adequate and reasonable. Although Ryan vainly sought the government's assistance in addressing the multiple-relator issues prior to settlement, she determined the settlement was fair, adequate and reasonable and it would be inappropriate to impede the settlement based upon her share dispute with the other relators. However, in my role as the Chief Investigator of this case, I was made aware of instances wherein various members of the government indicated they viewed Ryan as an exemplary relator whose unfailing cooperation merited a significant relator's share award at the culmination of the case. For example, on January 24, 2013, the U.S. Attorney's office EDPA, sent an email to James Hoyer partner John Newcomer advising that although the ultimate decision on relator's share is made by the Department of Justice, the EDPA would recommend, "Ms. Ryan receive a significant percentage recovery of the federal share of the civil settlement (both because of her role in the investigation and because of the duration of the investigation)." Retired FBI Agent Chris Mulhall has submitted a declaration in support of Ryan which affirms her invaluable contributions to this case. Former AUSA Sarah Lord has agreed to testify in support of Ryan if the Court sets the relator's share issue for oral arguments.

11. During the settlement process, I participated in or learned of multiple phone calls during which the government discussed its intentions regarding the relator's share issue. On one occasion, a representative of the EDPA advised the government would move to dismiss the complaints of Relators Weathersby and Dhillon following the settlement agreement. Later, a representative of the DOJ advised the government was unable to dismiss the complaint following the settlement, but would seek the Court's permission to enter a brief in which the government would assert Ryan was the first-filed relator. It was not until Ryan agreed to allow the

government to initiate the briefing schedule regarding the relator's share issue that the DOJ disclosed the government would be taking no position on who should be determined to be the first-filed relator.

12. During the 19 years I have worked at the James Hoyer firm, I have investigated or directed the investigation of approximately sixty False Claims Act cases. Based on my experience, Peggy Ryan's contributions to this case were exceptional. She was willing to take any steps the government asked of her to assist with its prosecution. She wore a surreptitious wire on her person to record more than two hundred hours of conversations and meetings over a three-year period. She remained in place at Endo while keeping her identity as a relator confidential from her colleagues and superiors. The high regard which she enjoyed at Endo enabled her to participate in meetings and conversations with senior management. Ryan accurately recounted the substance of meetings and conversations which the FBI was unable to record. She provided information enabling the government to target its subpoenas to obtain the most valuable information. And incredibly, she performed all of these stressful activities over a period of nine-years during which she suffered from ill health. Based upon the foregoing and my own extensive experience with numerous other relators, I can assert with a high degree of confidence that Peggy Ryan's efforts as a relator were nothing less than extraordinary.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 13<sup>TH</sup> day of November, 2014, at Tampa, FL.

  
Alfred Scudieri